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APR 2 1 2011

510(k) Summary
(in accordance with 21 CFR 807.92)

510(k) Number K110139

I. Applicant Information

Applicant:

CURVE DENTAL, INC.
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Calgary, AB T1T 4M2
Canada

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Managing Director
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Application Correspondent:

EMERGO GROUP INC.
611 West 5th Street, Third Floor
Austin, TX 78701
U.S.A.

Contact Person: Caroline Tontini
Project Manager
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Date Prepared: December 17, 2010

II. Device Name and Classification

Proprietary Name:	Curve Image
Classification Name:	Picture Archiving and Communications System
Common/Usual Name:	PACS
Classification:	Class II
Regulation Number:	892.2050
Product Codes:	LLZ
Classification Panel:	Radiology Devices

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III. Predicate Device

The Curve Image device is substantially equivalent to the following FDA cleared predicate devices with regard to indications for use, performance and technological characteristics:

510(k) Number:	K982422
Trade Name:	ChairSide Software Application
Manufacturer:	EagleSoft
Classification Name:	Picture Archiving and Communications System
Common/Usual Name:	PACS
Classification:	Class II
Regulation Number:	892.2050
Product Codes:	LLZ

510(k) Number:	K083018
Trade Name:	Centricity PACS Web Diagnostic (Web DX) PACS
Manufacturer:	GE Healthcare Dynamic Imaging Solutions
Classification Name:	Picture Archiving and Communications System
Common/Usual Name:	PACS
Classification:	Class II
Regulation Number:	892.2050
Product Codes:	LLZ

IV. Device Description

Curve Image is a web-based dental practice image management system that provides Internet access to an image library for each patient in a practice. It also provides tools for dental practices to manipulate patient images and both acquire and upload new images in industry standard formats. Images can be annotated and tagged, and are available for both diagnostic and non-diagnostic use. All of these actions are performed from a secure website, after entering user credentials, similar to other commonly used online applications. The system can be accessed by the user via an internet connection and does not require any software installation on the user's computer.

Curve Image may be sold as a stand-alone product, or may be bundled with a suite of web applications to form a comprehensive dental practice management application called "Curve Hero". Curve Hero is a patient scheduling and billing application that is provided as a stand-alone or in combination with Curve Image. Curve Hero is not a medical device and therefore is outside the scope of this submission.

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V. Intended Use

Curve Image is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audit recording and clinical exam data. The system uses a Web-based interface and includes the editing and storage of digital images. The system is designed to be a single source solution for a dental practice.

Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images cannot be acquired from standard dental imaging devices, but can be uploaded directly from the user's computer. Images can be edited (e.g., resized, contrast, cropped, etc.), as well as exported.

VI. Summary of the Technical Characteristics

Curve Image software provides the following high-level features:

- Browsing Images by Date and/or Source
- Viewing an Image
- Uploading an Image File
- Acquiring an Image from a Web Camera
- Acquiring an Image from a TWAIN Device
- Copying an Image to the Local Computer
- Saving a Modified Image
- Annotating an Image
- Zooming In on an Image
- Cropping an Image
- Inverting Colors of an Image
- Rotating an Image (increments of 90 degrees)
- Flipping an Image Horizontally or Vertically
- Increasing/Decreasing Image Brightness
- Increasing/Decreasing Image Contrast

The main technical characteristics of the software are:

- Web-based Application and Interface
- Secure Data Transmission (HTTPS)
- Server-Side Processing
- Database Management and Storage
- Secure Server Infrastructure

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VII. Summary of Non-Clinical Testing

Curve Dental, Inc. has conducted extensive non-clinical and validation testing of the Curve Image system, as a PACS system that is capable of providing reliable post-processing and display of images for dental applications. All of the different components of the Curve Image software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate in a manner substantially equivalent to the predicate devices.

The tests performed included:

- Product Risk Assessment
- Software modules verification tests
- Software validation test

VIII. Conclusions

Based on the comparison of intended use and technological characteristics, the Curve Image system is substantially equivalent to the ChairSide Software Application manufactured by EagleSoft (K982422) and the Centricity PACS Web Diagnostic (Web DX) PACS manufactured by GE Healthcare Dynamic Imaging Solutions.

Curve Image combines the web-based technology of the Centricity PACS, with the features and functionality of the ChairSide Software. Therefore the Curve Image device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Caroline Tontini
Project Manager
EMERGO Group, Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

APR 21 2011

Re: K110139
Trade/Device Name: CURVE IMAGE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 6, 2011
Received: April 8, 2011

Dear Ms. Tontini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indication for Use Statement

510(k) Number (if known): K110139

Device Name: **CURVE IMAGE**

Indications for Use:

CURVE IMAGE is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts, treatment plans, clinical notes, audit recording and clinical exam data. The system uses a Web-based interface and includes the editing and storage of digital images. The system is designed to be a single source solution for a dental practice.

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Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110139

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)